



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	2B05.R1
True Name	Bordetella Bronchiseptica Bacterial Extract, Subunit
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Vanguard Recombishield Injectable Bordetella - No distributor specified
Date of Compilation Summary	February 27, 2025

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy						
Pertaining to	<i>Bordetella bronchiseptica</i> (<i>B. bronchiseptica</i>)						
Study Purpose	Demonstrate efficacy against respiratory disease due to <i>Bordetella bronchiseptica</i>						
Product Administration	Two doses administered subcutaneously.						
Study Animals	40 dogs, approximately 8 weeks of age, were randomly assigned to either a control group or a vaccinate group (20 animals/group).						
Challenge Description	Animals were challenged with <i>B. bronchiseptica</i> 3 weeks after second vaccination.						
Interval observed after challenge	Animals were observed twice daily for 28 days for clinical signs of respiratory disease (cough).						
Results	<p><u>Table 1: Frequency Distribution of Cough due to <i>B. bronchiseptica</i> Challenge</u></p> <table border="1"> <thead> <tr> <th>Treatment Group</th><th>Cough (2 or more consecutive days)*</th></tr> </thead> <tbody> <tr> <td>Control</td><td>16/20 (80%)</td></tr> <tr> <td>Vaccinate</td><td>1/20 (5%)</td></tr> </tbody> </table> <p>*Dogs were considered to be positive if coughing persisted for 2 or more consecutive days.</p> <p>Please see attached pages for individual animal data.</p>	Treatment Group	Cough (2 or more consecutive days)*	Control	16/20 (80%)	Vaccinate	1/20 (5%)
Treatment Group	Cough (2 or more consecutive days)*						
Control	16/20 (80%)						
Vaccinate	1/20 (5%)						
USDA Approval Date	March 21, 2023						

Table 2: Cough Scores Post-Challenge (The score of (0) indicates no cough, (1) mild, (2) moderate, and (3) severe). Study Day (SD)

	Animal	TRT	SD 41	SD 42	SD 43	SD 44	SD 45	SD 46	SD 47	SD 48	SD 49	SD 50	SD 51	SD 52	SD 53	SD 54	SD 55	SD 56	SD 57	SD 58	SD 59	SD 60	SD 61	SD 62	SD 63	SD 64	SD 65	SD 66	SD 67	SD 68	SD 69	SD 70	
	am	pre	post	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm
	QUH2	T01	0	0	0	0	0	0	0	0	2	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	QVH2	T01	0	0	0	0	0	0	2	2	0	1	0	0	1	0	0	0	0	0	2	0	0	0	2	0	0	0	2	0	0	0	
	QXG2	T01	0	0	0	0	0	0	2	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	QZG2	T01	0	0	0	0	0	0	2	2	2	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	
	RBG2	T01	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	
	RCG2	T01	0	0	0	0	0	2	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	RHH2	T01	0	0	0	0	0	0	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	RJH2	T01	0	0	0	0	0	0	3	2	0	2	2	0	0	0	0	0	0	0	0	2	2	0	0	0	0	0	0	0	0	0	
	RKH2	T01	0	0	0	0	0	0	1	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	RKG2	T01	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	RQH2	T01	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	RRG2	T01	0	0	0	0	0	0	2	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	RTG2	T01	0	0	0	0	0	0	2	2	2	3	2	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	
	RWG2	T01	0	0	0	0	0	0	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	RWH2	T01	0	0	0	0	0	0	2	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	SDG2	T01	0	0	0	0	0	0	0	3	2	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	SFG2	T01	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	SGG2	T01	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	SLG2	T01	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	SLH2	T01	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	TYH2	T01	0	0	0	0	0	0	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	TZH2	T01	0	0	0	0	0	0	2	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	UQH2	T01	0	0	0	0	0	0	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	QSH2	T02	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	QTH2	T02	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	QWG2	T02	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	QYH2	T02	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	RAG2	T02	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	RHH2	T02	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	RLG2	T02	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	ROG2	T02	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	RPH2	T02	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	RSG2	T02	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	RXG2	T02	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	RZG2	T02	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	SEG2	T02	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	SGG2	T02	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	SHG2	T02	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	SGG2	T02	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	UAH2	T02	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	UBH2	T02	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	UCH2	T02	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	UPH2	T02	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

Study Type	Safety			
Pertaining to	ALL			
Study Purpose	To demonstrate safety under conditions of normal use.			
Product Administration	2 doses administered subcutaneously 3-4 weeks apart.			
Study Animals	Six hundred and twenty-four (624) dogs were enrolled in the study with 208 dogs being approximately 8 weeks of age and 416 dogs being 9 weeks of age or older.			
Challenge Description	N/A			
Interval observed after challenge	Immediate abnormal health events were assessed for approximately 10-20 minutes post vaccination. Dogs were observed for late abnormal health events after the first vaccination through 10 days post-second vaccination.			
Results	Table 1: Frequency Distribution of Immediate Reactions following Vaccination			
	Abnormal Health Events	Total Number of Events	% of Events	Total Number Vaccinations
	Anaphylaxis	0	0.00	1242
	Allergic Edema	0	0.00	1242
	Convulsion	0	0.00	1242
	Emesis	0	0.00	1242
	Injection Site Self-Trauma ^a	1	0.08	1242
	Other ^b	1	0.08	1242
	Vocalization at Administration	7	0.56	1242
	Vomiting	0	0.00	1242
	Wheals	0	0.00	1242
	^a Scratching, biting or rubbing at injection site.			
	^b Other was described as bleeding at the site of injection.			
	Table 2: Frequency Distributions of Abnormal Health Events – Overall			
	VEDDRA Preferred Term	Number of Animals	Total Number of Vaccinations	Percent (%)
Adipsia	1	1242	0.08	
Allergic oedema	1	1242	0.08	
Alopecia	1	1242	0.08	
Anorexia	8	1242	0.64	
Bacterial skin infection	7	1242	0.56	
Blepharitis	1	1242	0.08	
Claw / hoof / nail loss	1	1242	0.08	
Cough	2	1242	0.16	
Dehydration	2	1242	0.16	

	Dermatitis and eczema	4	1242	0.32
	Diarrhoea	15	1242	1.21
	Digestive tract disorder NOS	1	1242	0.08
	Emesis	14	1242	1.13
	Epileptic seizure	1	1242	0.08
	Flatulence, bloating and distension	1	1242	0.08
	Gastric dilation	1	1242	0.08
	Gastric torsion	1	1242	0.08
	Hypersalivation	1	1242	0.08
	Hyperthermia	1	1242	0.08
	Hypoglycaemia	1	1242	0.08
	Hypothermia	1	1242	0.08
	Inappropriate urination	1	1242	0.08
	Injection site oedema	1	1242	0.08
	Injection site pain	7	1242	0.56
	Injection site pruritus	2	1242	0.16
	Lameness	4	1242	0.32
	Lethargy	12	1242	0.97
	Localised pain NOS	1	1242	0.08
	Malodour	1	1242	0.08
	Mass NOS	1	1242	0.08
	Melaena	1	1242	0.08
	Murmur	2	1242	0.16
	Muscle tremor	2	1242	0.16
	Nausea	1	1242	0.08
	Oedema NOS	1	1242	0.08
	Osteosarcoma	1	1242	0.08
	Otitis NOS	2	1242	0.16
	Otitis externa	1	1242	0.08
	Otorrhoea	1	1242	0.08
	Pinnal irritation	1	1242	0.08
	Pulmonary disorder NOS	1	1242	0.08
	Respiratory tract disorder NOS	1	1242	0.08
	Retching	1	1242	0.08
	Seborrhoea	1	1242	0.08
	Skin disorders NOS	1	1242	0.08
	Skin oedema	1	1242	0.08
	Sneezing	3	1242	0.24
	Tooth disorder	2	1242	0.16
	Trauma NOS	2	1242	0.16
	Urine abnormalities NOS	1	1242	0.08
	NOS – Not Otherwise Specified			
USDA Approval Date	November 19, 2024			